

**Notice of Allowability**

Application No.

08/812,508

Examiner

Deepak Rao

Applicant(s)

PADIA, JANAK KHIMCHAND

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on November 4, 2004.
2. ☒ The allowed claim(s) ~~are~~ 76,77,80-83,85,86 and 89-92.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

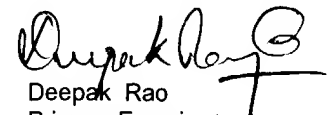
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
Deepak Rao  
Primary Examiner  
Art Unit: 1624

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Mehdi Ganjeizadeh on December 13, 2004.

The application has been amended as follows:

**In the specification:**

Insert the following as the first paragraph below the title of the invention:

-- This application is a continuation of application S. No. 08/545,241 filed November 21, 1995 now abandoned which is a continuation-in-part of application S. No. 08/364,624 filed December 27, 1994 now abandoned. --

**In the claims:**

In claim 76, last line, following 'j) 2-MeO-Ph', insert:

-- , or a pharmaceutically acceptable salt thereof --.

In claim 77, last line, following '1,1-dimethylethyl ester', insert:

-- , or a pharmaceutically acceptable salt thereof --.

Cancel claim 87.

*(Complete listing of claims as amended is enclosed in the Appendix)*

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

December 10, 2004

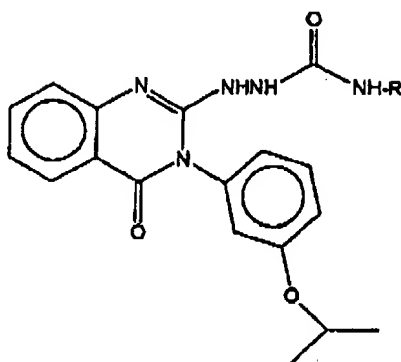
Art Unit: 1624

## Appendix

### Listing of Claims:

Claims 1-75 (cancelled).

76. (Currently amended) A compound having the structure and meanings for R as indicated:



wherein R is selected from the group consisting of:

- a) 4-BrPh;
- b) 4-COOEt-Ph;
- c) 4-CF<sub>3</sub>Ph;
- d) 3-Me-Ph;
- e) 3-COOEt-Ph;
- f) 3-COOtBu-Ph;
- g) 3-COOH-Ph;
- h) 4-MeO-Ph;
- i) 3-MeO-Ph; and
- j) 2-MeO-Ph.

or a pharmaceutically acceptable salt thereof.

77. (Currently amended) A compound selected from:

Hydrazinecarboxamide, N-(4-bromophenyl)-2-[3,4-dihydro-3-[3-(1-methylethoxy)phenyl]-4-oxo-2-quinazolinyl]-;

Benzoic acid, 3-[[[2-[3,4-dihydro-3-[3-(1-methylethoxy)phenyl]-4-oxo-2-quinazolinyl]hydrazino]carbonyl]amino]-ethyl ester;

Hydrazinecarboxamide, 2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]-N-(4-methoxyphenyl)-;

Hydrazinecarboxamide, 2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]-N-(3-methoxyphenyl)-;

Hydrazinecarboxamide, 2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]-N-(2-methoxyphenyl)-;

Hydrazinecarboxamide, 2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]-N-[(4-trifluoromethyl)phenyl]-;

Benzoic acid, 3-[[[2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]hydrazino]carbonyl]amino]-, 1,1-dimethylethyl ester;

Hydrazinecarboxamide, 2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]-N-(3-methylphenyl)-;

Benzoic acid, 4-[[[2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]hydrazino]carbonyl]amino]-ethyl ester;

Benzoic acid, 2-[[[2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]hydrazino]carbonyl]amino]-ethyl ester;

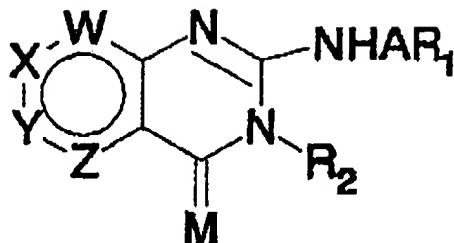
Benzoic acid, 3-[[[2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]hydrazino]carbonyl]amino]-; and

Benzoic acid, 3-[[[2-[3,4-dihydro-3-[3-(1-methoxy)phenyl]-4-oxo-2-quinazolinyl]hydrazino]carbonyl]amino]-

1,1-dimethylethyl ester, or a pharmaceutically acceptable salt thereof.

78 to 79 (Cancelled).

80. (Previously added): A method of reducing gastric acid secretion in a mammal comprising administering an effective gastric acid secretion reducing amount to a mammal in need thereof a compound of Formula I:



Formula

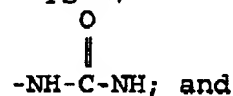
I

wherein W, X, Y, and

Z are C-R<sub>3</sub>, C-R<sub>4</sub>, C-R<sub>5</sub>, and C-R<sub>6</sub>;R<sub>3</sub>-R<sub>6</sub> are hydrogen;

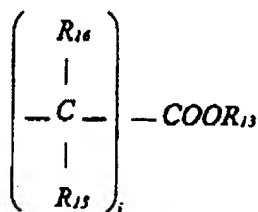
M is oxygen;

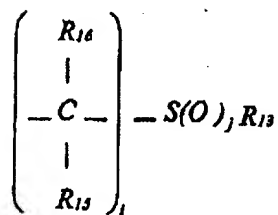
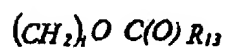
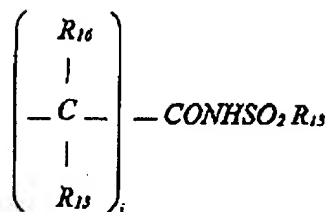
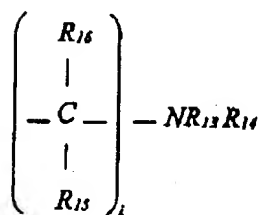
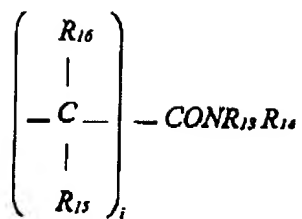
A is

R<sub>1</sub> and R<sub>2</sub> are substituted phenyl, wherein

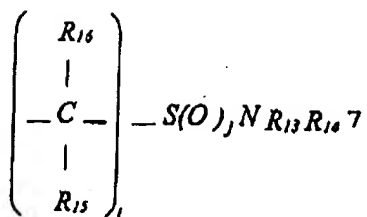
the substitutions are selected from

- hydrogen
- lower alkyl of 1-4 carbon atoms,
- (CH<sub>2</sub>)<sub>4</sub>OR<sub>13</sub>
- (CH<sub>2</sub>)<sub>4</sub>SR<sub>13</sub>
- trifluoromethyl
- nitro
- halo
- cyano
- azido
- acetyl





and

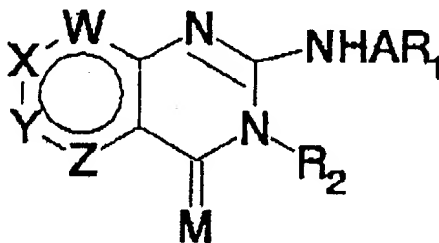


wherein  $i$  and  $j$  are independently 0, 1, 2,

$R_{13}$ ,  $R_{14}$ ,  $R_{15}$ ,  $R_{16}$  are each independently hydrogen, lower alkyl, alkaryl of from 7 to 10 carbon atoms; and

$NR_{13}R_{14}$  is also mono or bicyclic ring with one to four hetero atoms as N, O, S.

81. (Previously added): A method of reducing anxiety in a mammal, comprising administering an effective anxiety reducing amount to a mammal in need thereof a compound of Formula I:



Formula I

wherein W, X, Y, and Z are C- $R_3$ , C- $R_4$ , C- $R_5$ , and C- $R_6$ ;

$R_3$ - $R_6$  are hydrogen;

M is oxygen;

A is



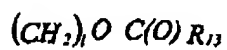
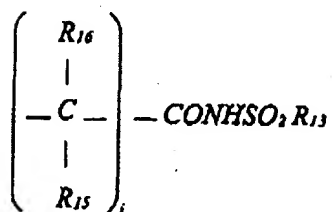
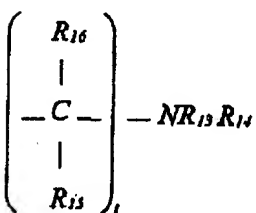
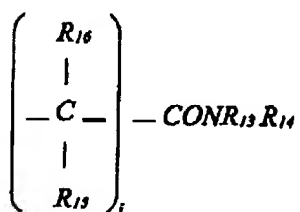
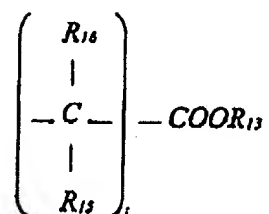
$R_1$  and  $R_2$  are substituted phenyl, wherein

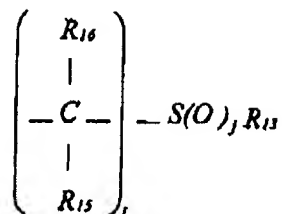
the substitutions are selected from

- hydrogen
- lower alkyl of 1-4 carbon atoms,
- $(CH_2)_4OR_{12}$

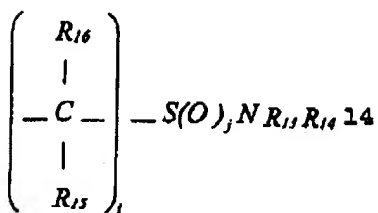


- $(CH_2)_iSR_{13}$
- trifluoromethyl
- nitro
- halo
- cyano
- azido
- acetyl





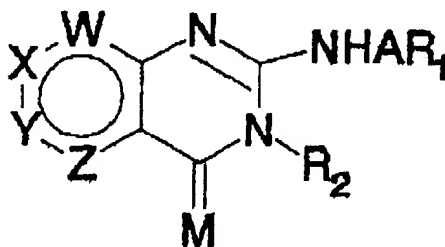
and



wherein  $i$  and  $j$  are independently 0, 1, 2,  
 $R_{13}$ ,  $R_{14}$ ,  $R_{15}$ ,  $R_{16}$  are each independently hydrogen, lower alky,  
 alkaryl of from 7 to 10 carbon atoms; and

$NR_{13}R_{14}$  is also mono or bicyclic ring with one to four  
 hetero atoms as N,O,S.

82. (Previously added): A method for treating  
 gastrointestinal ulcers in a mammal comprising administering an  
 effective gastrointestinal ulcer treating amount to a mammal in  
 need thereof a compound of Formula I:



Formula

I

wherein W, X, Y, and Z are C-R<sub>3</sub>, C-R<sub>4</sub>, C-R<sub>5</sub>, and C-R<sub>6</sub>;

$R_3-R_6$  are hydrogen;

M is oxygen;

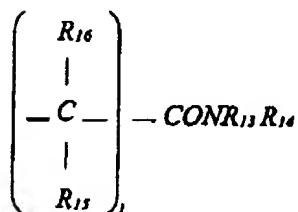
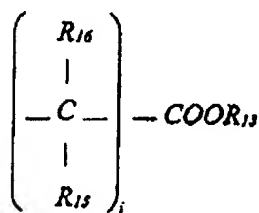
A is  $\begin{array}{c} \text{O} \\ | \end{array}$

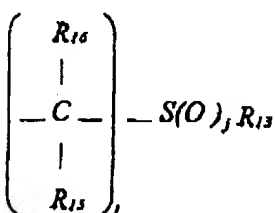
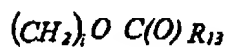
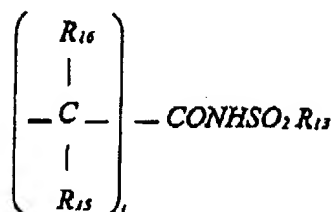
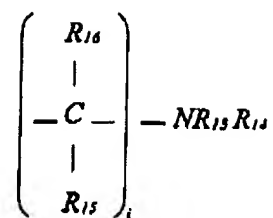
$-\text{NH}-\text{C}-\text{NH}-$ ; and

$R_1$  and  $R_2$  are substituted phenyl, wherein

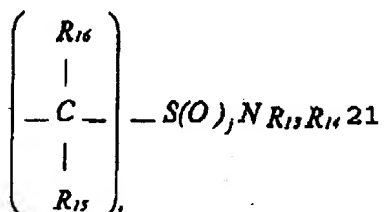
the substitutions are selected from

- hydrogen
- lower alkyl of 1-4 carbon atoms,
- $(\text{CH}_2)_4\text{OR}_{13}$
- $(\text{CH}_2)_4\text{SR}_{13}$
- trifluoromethyl
- nitro
- halo
- cyano
- azido
- acetyl





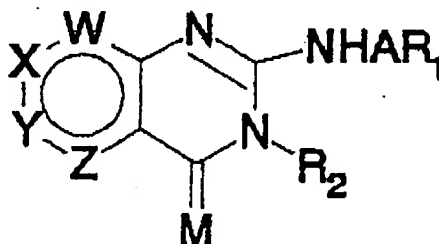
and



wherein  $i$  and  $j$  are independently 0, 1, 2,  
 $R_{13}$ ,  $R_{14}$ ,  $R_{15}$ ,  $R_{16}$  are each independently hydrogen, lower alky,  
 alkaryl of from 7 to 10 carbon atoms; and

$NR_{13}R_{14}$  is also mono or bicyclic ring with one to four  
 hetero atoms as N, O, S.

83. (Previously added): A method of treating psychosis in a mammal comprising administering an effective psychosis in a mammal comprising administering an effective psychosis treating amount to a mammal in need thereof a compound of Formula I:



Formula

I

wherein W, X, Y, and Z are C-R<sub>3</sub>, C-R<sub>4</sub>, C-R<sub>5</sub>, and C-R<sub>6</sub>;  
R<sub>3</sub>-R<sub>6</sub> are hydrogen;

M is oxygen;

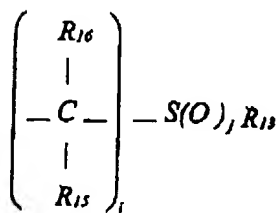
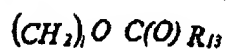
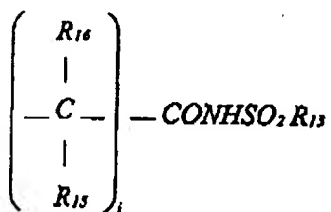
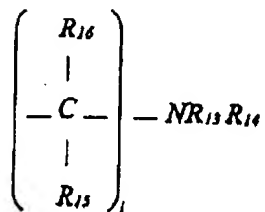
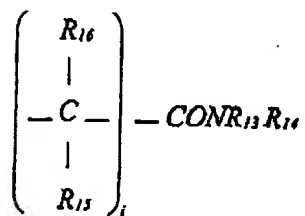
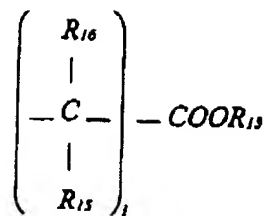
A is  $\begin{array}{c} \text{O} \\ | \end{array}$

$\begin{array}{c} | \\ \text{-NH-C-NH;} \end{array}$  and

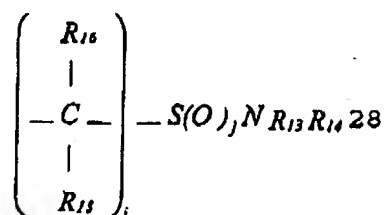
R<sub>1</sub> and R<sub>2</sub> are substituted phenyl, wherein

the substitutions are selected from

- hydrogen
- lower alkyl of 1-4 carbon atoms,
- (CH<sub>2</sub>)<sub>1</sub>OR<sub>13</sub>
- (CH<sub>2</sub>)<sub>1</sub>SR<sub>13</sub>
- trifluoromethyl
- nitro
- halo
- cyano
- azido
- acetyl



and

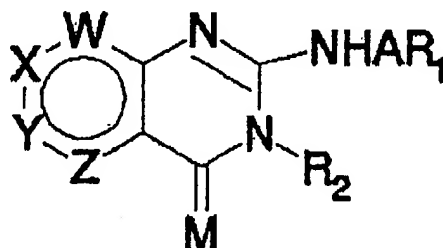


wherein  $i$  and  $j$  are independently 0, 1, 2,  
 $R_{13}$ ,  $R_{14}$ ,  $R_{15}$ ,  $R_{16}$  are each independently hydrogen, lower alky,  
 alkaryl of from 7 to 10 carbon atoms; and

$NR_{13}R_{14}$  is also mono or bicyclic ring with one to four  
 hetero atoms as N,O,S.

84 (Cancelled).

85. (Previously added): A method of treating pain in a  
 mammal comprising administering an effective amount to a mammal  
 in need thereof a compound of Formula I:



Formula I

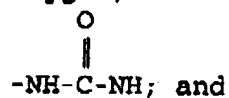
wherein wherein

W, X, Y, and Z are C- $R_3$ , C- $R_4$ , C- $R_5$ , and C- $R_6$ ;

$R_3$ - $R_6$  are hydrogen;

M is oxygen;

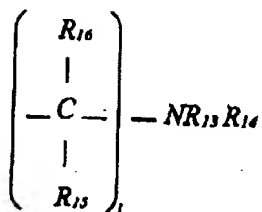
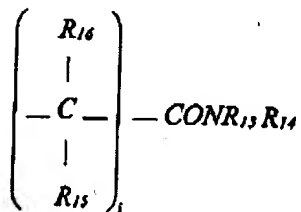
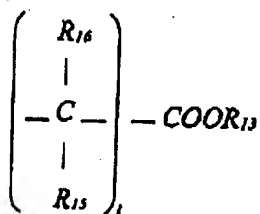
A is



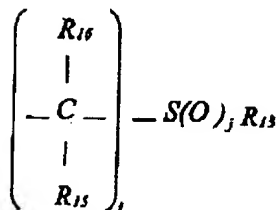
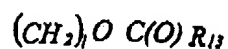
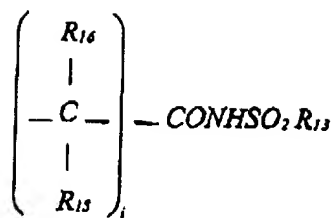
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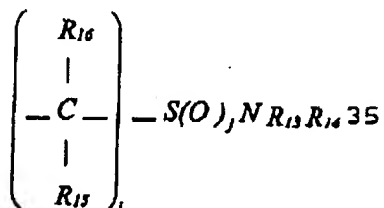
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- lower alkyl of 1-4 carbon atoms,
- $(\text{CH}_2)_4\text{OR}_{13}$
- $(\text{CH}_2)_4\text{SR}_{13}$
- trifluoromethyl
- nitro
- halo
- cyano
- azido
- acetyl







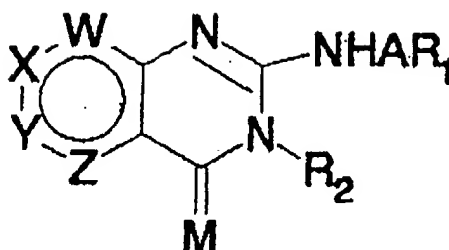
and



wherein  $i$  and  $j$  are independently 0, 1, 2,  
 $R_{13}$ ,  $R_{14}$ ,  $R_{15}$ ,  $R_{16}$  are each independently hydrogen, lower alky,  
 alkaryl of from 7 to 10 carbon atoms; and

$NR_{13}R_{14}$  is also mono or bicyclic ring with one to four  
 hetero atoms as N, O, S.

86. (Previously added): A method of treating panic in a  
 mammal comprising administering an effective amount to a mammal  
 in need thereof a compound of Formula I:



Formula

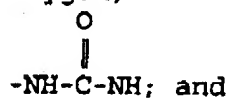
I

wherein W, X, Y,

and Z are C-R<sub>3</sub>, C-R<sub>4</sub>, C-R<sub>5</sub>, and C-R<sub>6</sub>;R<sub>3</sub>-R<sub>6</sub> are hydrogen;

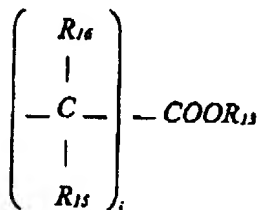
M is oxygen;

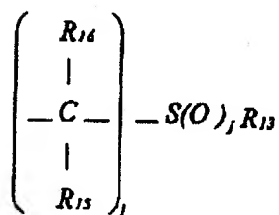
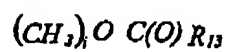
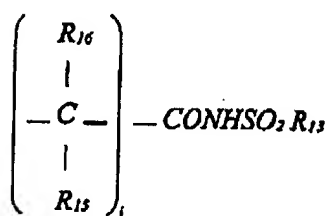
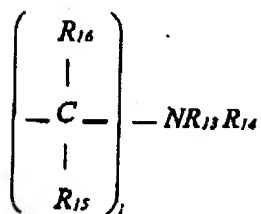
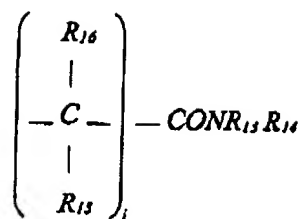
A is

R<sub>1</sub> and R<sub>2</sub> are substituted phenyl, wherein

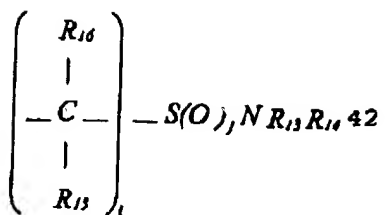
the substitutions are selected from

- hydrogen
- lower alkyl of 1-4 carbon atoms,
- (CH<sub>2</sub>)<sub>4</sub>OR<sub>13</sub>
- (CH<sub>2</sub>)<sub>4</sub>SR<sub>13</sub>
- trifluoromethyl
- nitro
- halo
- cyano
- azido
- acetyl





and



wherein i and j are independently 0, 1, 2,  
 $R_{13}$ ,  $R_{14}$ ,  $R_{15}$ ,  $R_{16}$  are each independently hydrogen, lower alky,  
 alkaryl of from 7 to 10 carbon atoms; and

$NR_{13}R_{14}$  is also mono or bicyclic ring with one to four  
 hetero atoms as N,O,S.

87. (Cancelled).

88 (Cancelled).

89. (New): A pharmaceutically acceptable salt of the  
 compound of claim 76.

90. (New): A pharmaceutically acceptable salt of the  
 compound of claim 77.

91. (New): A pharmaceutical composition comprising the  
 compound of claim 76 or a pharmaceutically acceptable salt  
 thereof and a pharmaceutically acceptable carrier.

92. (New): A pharmaceutical composition comprising the  
 compound of claim 77 or a pharmaceutically acceptable salt  
 thereof and a pharmaceutically acceptable carrier